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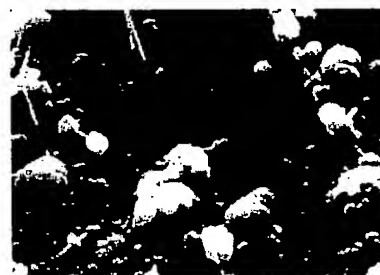
Bioglass[®]

Bioglass[®] Description & History

Bioglass[®] is a transparent bioactive material, consisting of silicon, sodium, calcium and phosphorus, developed by Dr. Larry Hench at the University of Florida, with proven abilities to bond to bone and connective tissue.

Bioactive Material Defined

A bioactive material is defined as "one that elicits a specific biological response at the interface of the material which results in the formation of a bond between the tissues and the material."



Mixed HCA agglomerates with collagen fiber deposition after one hour in vitro. (Photo By: Carlo Pantano)

How Bioglass[®] Works

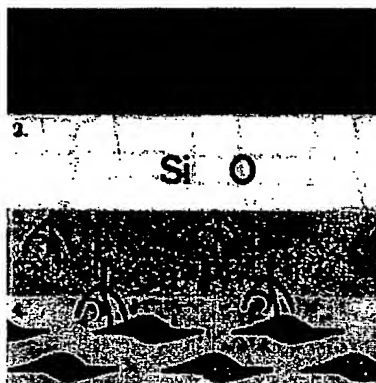
Upon Bioglass[®] contact with the body fluid there is an immediate exchange of ions which results in a physiochemical bond between Bioglass[®], soft tissue, and bone.

The ion exchange creates an environment resulting in the formation of a hydroxyl-carbonate apatite layer (HCA), a biological apatite identical to the mineral phase of bone, which allows for more rapid repair and regeneration of bone than other synthetic grafting materials.

HCA Layer Formation

The Bioglass[®]-initiated HCA layer is biologically equivalent to the mineral phase of human bone, and is therefore recognized by the body as being something natural, not synthetic. This formation of the HCA layer occurs concurrently with the biological processes of collagen deposition and cellular differentiation, resulting in chemical bonding and enhanced healing of the defect.

The Osteoproduktive Process



1. When Bioglass® is exposed to body fluids, an ion exchange occurs immediately with the surface.
2. Ion exchange causes release of sodium and calcium ions forming a silica gel layer within minutes.
3. Substituted hydroxy-carbonate-apatite develops which cannot be distinguished from the natural apatite of bones and teeth.
4. Cells produce collagen which becomes embedded in the layer, providing an adherent interface with Bioglass®. Osteoblasts lay down bone on this layer.

Proven Efficacy in Bone Regeneration

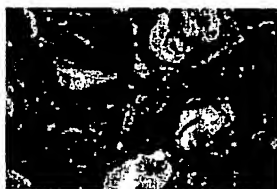
In a canine study, a mixture of Bioglass® particles and autogenous bone created 50% more bone formation than autogenous bone alone. In a sheep study, Bioglass®



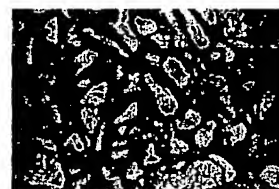
Bonding gradient interface of

particles placed adjacent to bleeding subchondral endplates produced identical results at 6 months when compared with a 50/50 mix of Bioglass® and autologous bone alone. 11 When compared with hydroxyapatite in a rabbit model, Bioglass® particles stimulated much more rapid bone growth than did HA particles. The repaired tissue was bone, not a composite of bone reinforced by the alloplastic material, such as is seen with hydroxyapatite granules.

Containing granules adjacent to HCA layer and rat tibia thirty days after implantation in critical size defect. BG=Bioglass®; S=silica-rich layer; CaP=calcium phosphorous-rich layer; O=osteoblasts; B=bone



At 12 weeks, all BG particles are connected by bone bridges from the periphery to the center of the defect; bone is filling much of the interparticular spaces (10x)

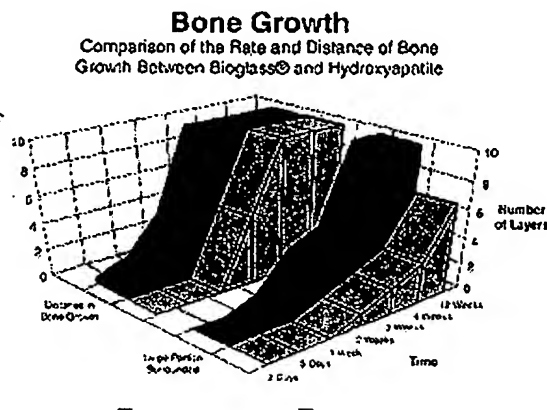


Histologic section showing new bone forming around Bioglass® (BG) at 4 weeks (modified Van Geisen stain, 10x magnification)

More Rapid Bone Growth

Oonishi et al created bilateral 6mm defects in the moral condyles of mature rabbits. Particulate Bioglass® and hydroxyapatite were placed in sufficient quantities to fill the defects, one material on each side. The animals were sacrificed at several intervals ranging from two days to twelve weeks. Specimens were observed by both light microscope study and backscattered scanning electron microscope imaging.

After two weeks, new bone is found throughout the assemblage of Bioglass® particles; in contrast, three weeks are required for bone to proliferate throughout the array of



hydroxyapatite granules. Additionally, the surrounding of large Bioglass® particles by bone is fully accomplished in six weeks; only 30% of large hydroxyapatite particles are surrounded during this period. Even after twelve weeks, only 60-70% of large hydroxyapatite particles are surrounded by new bone. An advantage of the particulate form of Bioglass® appears to be that it becomes incorporated into the growing bone as its components are used up by the new bone. The rapid response of the body to Bioglass® and the structurally normal bone tissue produced should prove clinically advantageous to results obtained with hydroxyapatite .

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